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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,693	02/23/2004	Michael D. Modglin	57590.US / 1720.0	1303
408 7590 03/18/2008 LUEDEKA, NEELY & GRAHAM, P.C. P O BOX 1871 KNOXVILLE, TN 37901				
EXAMINER JACKSON, BRANDON LEE				
ART UNIT		PAPER NUMBER		
3772				
MAIL DATE		DELIVERY MODE		
03/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/784,693

**Applicant(s)**

MODGLIN, MICHAEL D.

**Examiner**

BRANDON JACKSON

**Art Unit**

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/15/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to amendments/arguments filed 11/15/2007.

Currently, claims 1-19 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/2007 has been entered.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4-9, 11-13, 15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweardy et al. US 6,921,376 in view of Burns Re. 34,714. Tweardy discloses a cervical collar (Fig. 1A) comprising; a posterior portion (col. 3, lines 49-51) generally configured to conform to a rear neck portion of a patient, the posterior portion comprising an upper posterior segment (200) having an upper posterior rigid member

(204) connected to an upper posterior laminate body (202) and a lower posterior segment (300) comprising a lower posterior rigid member connected to a lower posterior laminate body, wherein the upper posterior rigid member is adjustably securable to the lower posterior rigid member and the upper posterior laminate body is adjustably securable to the lower posterior laminate body, with the upper and lower posterior laminate bodies each comprising a laminated structure having a polymeric sheet material, a foam material, and a fabric material; and an anterior portion (100, col. 3, lines 44-48) generally configured to conform to a chin and front neck portion of the patient, the anterior portion comprising an upper anterior segment (106) having an upper anterior rigid member (see chin strut 102, col. 4, lines 22-24) connected to an upper anterior laminate body (106) and a lower anterior segment (108) comprising a lower anterior rigid member connected to a lower anterior laminate body, wherein the upper anterior rigid member is adjustably securable to the lower anterior rigid member (101, col. 4, lines 62-66) and the upper anterior laminate body is adjustably securable to the lower anterior laminate body, with the upper and lower anterior laminate bodies each comprising a laminated structure having a polymeric sheet material (col. 5, lines 1-7) and a fabric material (col. 5, lines 7-10).

Tweardy et al. do not expressly state that the laminated structures have a sheet material, foam material and fabric material as layers of the laminate. Burns teaches a cervical collar with laminate bodies. Burns teaches that the laminate bodies are made of layers of different material (abs). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the laminated structures of Tweardy

et al. to be laminate structures made of layers of materials held together by adhesive as taught by Burns for the purpose of increased support, durability, and comfort (col. 1, lines 26-30). As to the layers being made by molding with adhesive between the layers this is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thrope, 777 F.2d 695, 698, 227 USPQ964, 966 (Fed. Cir. 1985)(citations omitted).

As to claim 4, the upper and lower posterior rigid member each comprise substantially rigid plastic member (struts, 102).

As to claim 5, the upper and lower anterior rigid member each comprise substantially rigid plastic members (struts, 202).

As to claims 6 and 7, the upper posterior and upper anterior rigid member may comprise fasteners releasably engageable with the aperture (col. 4, lines 1-5).

As to claim 8, the upper posterior laminate body and the lower posterior laminate body have matingly positionable surfaces that are releasably attachable to one another for permitting the laminate bodies to be adjustably positionable (via buckle or fastener or rivets, fig. 1A) relative to one another.

As to claim 9, the upper anterior laminate body and the lower anterior laminate body have matingly positionable surfaces that are releasably attachable to one another for permitting the laminate bodies to be adjustably positionable relative to one another.

As to claim 11, the collar comprises straps (205) for maintaining the anterior portions in an overlapped orientation when installed on a user.

As to claim 12, the collar comprises a supplemental strap system (322,334) configured to extend between portions of the posterior portion and the anterior portion and to extend adjacent an under-arm region of a user.

As to claim 17, the medical support comprises a strap (205) wherein the laminate body is substantially flexible in an untensioned state so as to be positionable about a portion of a user, yet which becomes sufficiently rigid when positioned about the portion of a user and tensions as by the use of the strap.

As to claim 18, the invention of Tweardy et al. is a support in comprising a cervical collar.

Claims 2, 3, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tweardy et al. and Burns in view of Calabrese US 2005/0101896. As to claims 2, 3, 14 and 16 Tweardy et al. and Burns disclose the limitations of the base claim but do not expressly state that the laminate bodies comprise a low density polyethylene material. However, Calabrese teaches a cervical collar with low density polyethylene material. It would have been obvious to one having ordinary skill in the art at the time of the invention to a material such as low density polyethylene in the cervical

collar of Tewardy et al. and Burns as taught by Calabrese for the purpose of providing the user with a lightweight material for increased comfort ([0002],[0014]).

Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tewardy/Burns as applied to claim 1 above, and further in view of Garth et al. (US Patent 6,315,746). Teward/Burns does not explicitly state the lower laminate body is generally U-shaped, with the upper portion of the u having outwardly extending arms and the bottom of the U having a bifoliar configuration. However, Garth et al. teaches a cervical orthosis (100) comprising a lower laminate body (151) that is generally U-shaped (fig. 1) with the upper portion having outwardly extending arms (fig. 1) and the a bifoliar configuration (fig. 1) on the lower portion. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Tewardy/Burns lower laminate to have the configuration as taught by Garth et al. in order to better configure the geometry of the user. Moreover, it would have been an obvious matter of design choice to make the different portions of the cervical device of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson  
Examiner  
Art Unit 3772

BLJ

/Brandon Jackson/  
Examiner Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772